DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 16 2005

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C. Elaine Jones, Ph.D.
Vice President, US Regulatory Affairs
William M. Zoffer
Vice President, Assistant General Counsel
GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Re: Docket No. 2004P-0523/CP1

Dear Ms. Jones and Mr. Zoffer:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated November 24, 2004. Your petition requests that the Agency refrain from approving any ANDAs for fluticasone propionate nasal spray, unless the product is shown to meet the same standards of product quality (i.e., specifications for droplet size distribution and spray pattern) and consistency (i.e., low variability) as those approved for Flonase in October 2004 (supplement S-019 to NDA 20-121).

FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0523

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